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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,865	12/08/2000	Edwin Oscar Schraa	2578-4257.IUS	3138

24247 7590 06/21/2002

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EXAMINER

LI, QIAN J

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/21/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,865

Applicant(s)

SCHRAA ET AL.

Examiner

Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1-3, 5, 7-10, and 13 are directed to a kit, comprising a first nucleic acid comprising a gene to be delivered to a recipient cell in a host, and a second gene delivery vehicle essentially identical to said first nucleic acid, but lacking said gene; and a method comprising administering to a host the second gene delivery vehicle lacking said gene to be delivered, and after a period of time, administering to the host the first gene delivery vehicle. Classified in Class 514, subclass 44.
- II. Claims 1 and 4 are directed to a kit, comprising a first nucleic acid comprising a gene to be delivered to a recipient cell in a host, and a second gene delivery vehicle essentially identical to said first nucleic acid, wherein the second vehicle comprises a nucleic acid encoding an indifferent protein. Classified in Class 435, subclass 320.1.
- III. Claims 1 and 6 are directed to a kit, comprising a number of first gene delivery vehicles comprising genes to be delivered to a recipient cell in a host, wherein the number is above the number that can be neutralized by a humoral response of the host, and a second gene delivery vehicle essentially identical to said first nucleic acid, but lacking said gene. Classified in Class 435, subclass 320.1.

- IV. Claim 8 is directed to a method, comprising administering to a host a first gene delivery vehicle having said gene to be delivered, and after a period of time, administering to the host a second gene delivery vehicle that is essentially the same as the first. Classified in Class 514, subclass 44.
- V. Claim 11 is directed to a method for the treatment of diseases associated with uncontrolled proliferation of cells in a host. Classified in Class 514, subclass 44.
- VI. Claim 12 is directed to a method for the treatment of diseases associated with a genetic defect in a host. Classified in Class 514, subclass 44.
- VII. Claims 14-26 are directed to a method for the preparation of a kit. Classified in Class 435, subclass 471.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II, III, and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the groups I-III are drawn to a different product, which comprising a different first or second component in the kit. The different products are distinct in chemical structure and functional characteristics, as well as modes of operation when used as therapeutic agents.

Inventions IV-VII and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

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806.04, MPEP § 808.01). In the instant case, groups I, IV-VI are drawn to an *in vivo* method, group VII is drawn to an *in vitro* method. Each of the groups differs either in the materials used in the process, or the method steps (in vivo vs. ex vivo, method of gene delivery, and method of making a gene delivery vehicle, etc). The different methods use material different substances, have different method steps, different modes of operation, and have distinct technical considerations, and search criteria.

The differences of the Inventions I-VII are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
June 10, 2002


JAMES KETTER
PRIMARY EXAMINER